EVALUATION OF SONOSALPINGOGRAPHY AS A SCREENING TEST FOR TUBAL PATENCY IN COMPARISON WITH HYSTEROSALPINGOGRAPHY

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CERTIFICATE

This is to certify that the dissertation entitled **"EVALUATION OF SONOSALPINGOGRAPHY AS A SCREENING TEST FOR TUBAL PATENCY IN COMPARISON WITH HYSTEROSALPINGOGRAPHY"** *submitted by* ***Dr. N.T. VAANI*** *to the Faculty of Obstetrics and Gynaecology, The Tamilnadu Dr. M.G.R. Medical university, Chennai in partial fulfillment of the requirement for the award of M.D. Degree Branch II (Obstetrics and Gynaecology) is a bonafide research work carried out by her during the period of January 2004 to December 2004 under our direct supervision and guidance.*

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CONTENTS

INTRODUCTION

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Infertility is defined as one year of unprotected intercourse without pregnancy. As this is a reversible condition it is also known as sub fertility. Reproduction is a biological function of the female. When this is not achieved she is under psychological trauma and looses social status.

Infertility is seldom if ever, a physically debilitating disease. It may however severely affect the couple's psychological harmony, sexual life and social function. Even in those societies which made family planning and birth control their official policy, the individual couple desiring a child but unable to conceive feel deprived and bitter.

In our culture childlessness may cast a heavy shadow on the psychological and social adequacy of the female and diminishes the social standing of the male.

Most cultures regard children as an extension of self, as bearers and perpetuators of the family name and tradition as well as an expansion of one's hopes, aims and strivings. The inability to procreate is thus always, perceived as a denial of basic right and a disappointment, sometime bordering on grief.

Since the beginning of history, the human race placed emphasis on fertility. In the Judeo Christian tradition, the importance of procreation is inherent. Man's very creation "God created male and female in his own image", God blessed them and said unto them "Be fruitful and multiply and replenish the earth and subdue it". The grief of a woman who failed to bear a live born child is no less in modern society than it was for our forefathers (Vaclav Insler 1993).

Since about 30-40% of infertility in the female is attributed to tubal factor, evaluation of the tubal function is the prime importance in the investigation of infertility.

An ideal method should offer a means of positive and definitive diagnosis of tubal patency or occlusion or uterotubal abnormalities that can be related to infertility. (Clifford 1953)

The development of ultrasound has provided the clinician with the opportunity to visualise the pelvic reproductive organs non-invasively. Determining whether the fallopian tubes are patent is part of the initial evaluation procedure in seeking the cause of infertility.

AIM OF STUDY

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1. To critically evaluate the specificity of employing sonosalpingography in assessment of tubal patency.

2. To compare the accuracy, efficacy, positive predictive value of sonosalpingography with hysterosalpingography in assessment of tubal patency.

3. To evaluate sonosalpingography as a minimally invasive screening test in assessment of tubal patency.

INFERTILITY – ETIOLOGY AND EVALUATION

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Infertility is defined as one year of unprotected intercourse without conception. This is further classified as primary infertility, in which no previous pregnancies have occurred, and secondary infertility, in which a prior pregnancy, although not necessarily a live birth, has occurred. Fecundability is the probability of achieving pregnancy in a single menstrual cycle, which is 20-25%. Fecundity is the probability of achieving a live birth in a single cycle. Based on this 90% of couple achieve conception in 12 months. The incidence of infertility is 10% but may vary in different countries.

The extent of female and male infertility are as follows. Female cause alone is found in 40-55%, male cause alone in 25-40%, fault in both partners found in 10% and no cause could be elicited in 10% of couples.

Etiology of infertility

Female cause alone	40-55%
Male cause alone	25-40%

Both partners	10%
Unexplained infertility	10%

Causes of infertility in the female are, tubal factor contribute 30 – 50%, ovarian factor 15 – 24%, uterine and endometrial factor 5 – 10%, cervical factor 1 – 2%, immunological, psychological and unexplained infertility are the rest of 10% (Lulu – Al – Nuain, 1998).

Cause of female infertility

Tubal factor	30 – 50%
Ovarian	15 – 24%
Uterine & endometrial	5 – 10%
Cervical	1 – 2%
Immunological unexplained	5 – 15%

Etiology varies depending on natural, cultural and socio economic differences (W.R. Jones - 1995).

Tubal dysfunction accounts for 30-40% of cases of infertility, since ovum pick up, ovum transport, sperm transport, fertilization, embryo transport and early development of embryo occur in the tube.

I. Anatomy of fallopian tube:

The first accurate description of the oviduct was provided by Gabriele Falloppie

in his "Observations Anatomicae" in 1561.

Each fallopian tube extends outwards from the uterine cornua to end near the ovary. At the abdominal ostium the tube opens into the peritoneal cavity, which is therefore in communication with the exterior of the body through the uterus and the vagina. The tubes or oviducts convey the ovum from the ovary towards the uterus, which provides oxygenation and nutrition for sperm, ovum and zygote if fertilization occurs.

The fallopian tube runs in the upper margin of the broad ligament, part of which is known as the mesosalpinx, which encloses it so that the tube is completely covered with peritoneum except for a narrow strip along this inferior aspect.

Each tube is about 10 cm long and is described in four parts.

1. The interstitial portion.
2. The isthmus
3. The Ampulla
4. The infundibulum or fimbrial portion

Fimbriae

The abdominal ostium of the tube is surrounded by fimbriae. This segment is rich in folds but poor in muscle fibers, with thin outer longitudinal and inner circular

layers. The epithelium is densely ciliated, with ciliated cells, which beat uniformly towards the uterus. One of the fimbriae is longer than the others and extends to, and partly embraces the ovary.

Ampulla

Ampulla is the longest of the tubal segments, representing approximately 60% of its length. The lumen diameter varies from 1-2 mm at the isthumo ampullary junction to 1 cm near the infundibulum. They have a rich network of blood vessels and lymphatics. The mucosa is densely ciliated with 40-60% of the total epithelial cells bearing cilia.

The muscle fibres are arranged in three layers comprising an outer longitudinal layer, a middle circular and an incomplete inner longitudinal layer.

Isthmus

The lumen of the isthmus averages 0.5 mm but can be as narrow as 0.1 mm, and the muscle layer is well developed. The mucosal folds are usually 3 in number and the ciliated cells comprise only 20 – 25% of the epithelial cells.

Intramural segment

The intramural or interstitial segment of the uterine tube may have a straight, curved or convoluted course ending in a rounded or fish mouthed opening at each cornual angle of the uterus. The muscular wall is composed of an inner and outer

longitudinal layer with an intermediate circular layer arranged in spiral fashion.

There is a marked decrease in the number of ciliated cells and the secretory cells tend to be flattened and assume a polygonal, elongated shape.

II. Physiology of the fallopian tube:

The fallopian tubes play an important role in reproduction. The fallopian tube has the complex task of ensuring the transport of spermatozoa towards the ovary and of ova towards the uterus. After ovulation, the fimbriae pick up the oocyte from the peritoneal fluid that has accumulated in the cul-de-sac. The epithelial ciliae transport the oocyte up to the Ampulla. The capacitated spermatozoa are transported from the endometrium through the cornual section and advanced through the fallopian tube into the Ampulla, where fertilization occurs. The embryo initiates its early clevage and is propelled to the endometrial cavity at the blastocyst stage.

The fallopian tube supports the changes in the gametes, which leads to fertilization, embryo cleavage and transport of the zygote towards the normal site of implantation in the uterine endometrium.

III. Tubal pathology:

A. PID

Damage resulting from infection is the commonest cause of tubal infertility, Salpingitis occurs more commonly in younger women.

Salpingitis may present in an acute or chronic form or as an acute exacerbation of a chronic infection. Salpingitis can also occur as a result of adjacent or distant inflammatory processes. Tubal occlusion may occur secondary to the neighbouring peritoneal reaction.

Most common causes are sexually transmitted non specific infection. Salphingitis may also be caused by irritants or drugs introduced during drug insufflation or surgery. Tuberclosis also contribute significantly to tubal damage.

Infertility occurs in 13% of patients who have had single episode of infection. The incidence increases to 35% after two episodes and 75% after three or more episodes.

Whatever be the aetiology, the sequelae of salpingitis, which damage the distal portions of the fallopian tube, include hydrosalpinx, pyosalpinx, fimbrial partial obstruction. When the proximal segments of the tube are principally involved, the end results include isthmic and cornual stenosis and blockage.

B. Hydrosalpinx

Hydrosalpinx caused by distal tubal blockage is a major cause of infertility. Obstruction of the distal end of the fallopian tubes accounts for accumulation of the normally secreted tubal fluid, creating distention of the tube with subsequent damage of the epithelial ciliae. Hydrosalpinx may have either thin or thick walls. In both types terminal part of the tube is totally blocked and fimbriae are obscured.

C. Proximal tubal pathology

Proximal tubal pathology occurs less often than lesions of the distal end.

Causes

1. Obliterative fibrosis
2. Salpingitis isthmica nodosa
3. Chronic tubal inflammation
4. Endometriosis

Less frequent causes are

1. Tubo cornual polypi
2. Tuberculosis
3. Remnants of a chronic tubal pregnancy

The above mentioned causes affect the intramural segment and the isthumus, which can cause infertility without necessarily producing complete obstruction of the

lumen.

Assessment of Tubal Patency

There are essentially 3 categories of tubal patency test. They are

I. Where a test medium is flushed through the cervix into the tubes via the uterine cavity.

II. Direct cannulation of the fallopian tube

III. Tests dependent on the transport of particles

I. Where a test medium is flushed through the cervix into the tubes via a uterine cavity.

a) Gas Hydrotubation (Rubin's Test)

b) Phenol Sulphonapthalein (PSP) Test (The Speck Test)

c) Methylene blue test

d) Hysterosalpingography

e) Laparoscopic chromopertubation

f) Sonosalpingography

II. Direct canulation

Hysteroscopic / Radiologic control / tactile control with ultrasonic confirmation.

III. Tests dependent on transport of particles

It is divided into **Ascending tests**, when the particles are placed at the cervix and patency is suggested by finding them in the abdominal cavity.

a) Microsphere migration

b) Detection of sperm by culdocentesis or endoscopy within the pouch of douglas.

Descending tests

- ★ Starch test
- ★ Gold microsphere test

Where a test medium is flushed through the cervix into the tubes via the uterine cavity

a) Gas Hydrotubation (Rubin's test)

Utero tubal insufflation as a clinical non-operative test was introduced by I.C. Rubin in 1919. Initially Rubin used oxygen, since it was considered unsafe, later carbon dioxide was used.

Tubal patency was confirmed by patient complaining of abdominal and shoulder tip pain, due to irritation of the peritoneum by the gas. Auscultation over each iliac

fossa would reveal bubbling sounds as gas escaped from the tubes.

An erect x-ray revealed sub diaphragmatic gas. An adaptation to this technique is to measure the pressure of the insufflating gas using kymography.

Advantage

- ★ This is a simple technical procedure.

Disadvantage

- ★ Leakage of gas from apparatus and out of the cervix.
- ★ Not possible to differentiate between unilateral and bilateral tubal patency.

b) Phenolsulphonaphthalein (PSP) Test (The Speck Test)

PSP is absorbed rapidly from the peritoneal cavity but poorly from the reproductive tract.

Technique

A saline solution of PSP is infused into the uterus. The presence of the chemical in urine will suggest tubal patency and can be shown by the urine developing a pink color on adding 10% NaOH.

Advantage

Simple technical procedure

Disadvantage

PSP can be absorbed from the mucosa of the hydrosalpinges giving a false positive result of tubal patency. It is impossible to differentiate between unilateral and bilateral tubal patency.

c) Methylene blue test

Technique

Methylene blue injected into the uterine cavity can be detected in the pouch of douglas by culdocentesis if there is tubal patency.

Advantage

Simple procedure

Disadvantage

1. It is impossible to differentiate between unilateral and bilateral patency.
2. There is failure rate of performing culdocentesis effectively.

d) Hysterosalpingography

In 1909 Nemenow was the first to suggest the introduction of Lugol's solution into the uterine cavity in order to obtain x-ray film of the hallow organ.

In 1914 Rubin introduced the use of collargol as a contrast medium for demonstrating tubal patency. In 1921 lipiodol was introduced by Sicard and Forestier.

Over a period of many years there is improvement in contrast media and their usage.

Few water soluble contrast media are

1. Hypaque
2. Urograffin 60% and 70%
3. Canray 280 and 420

e) Laparoscopic chromopertubation

Endoscopic tubal patency testing was first made popular with the use of culdoscope, but this method has fallen from general use. Laparoscopic chromopertubation was first widely used in early 1970s and is the main form of tubal

assessment in many centers.

Laparoscopic examination of the pelvis and dye test for tubal patency can be combined with dilatation of uterine cervix, sounding and exploring the uterine cavity and endometrial biopsy. Laparoscopic visualization of pelvis allows diagnosis of intraperitoneal mechanical or physical abnormalities especially endometriosis and pelvic adhesions. Omental and bowel adhesion is noted and their sites and extent of attachment to other surfaces described, thickness, vascularity and reduced mobility of uterus, tubes and ovaries noted. The uterus is inspected for size, shape, irregularity, presence of leiomyomata and congenital abnormalities.

The procedure can be combined with salpingography and / or hysteroscopy.

Correct timing of the investigation will enable evidence of ovulation to be obtained by visualization of a corpus luteum. There is no exposure to radiation.

Disadvantages

1. This is an invasive test requiring a general anaesthetic with its associated risks.
2. Not always possible to determine the actual site of occlusion in any tube.

Investigation of tubal patency using ultra sound

Both transabdominal and transvaginal ultrasound have been described as modes of assessment of tubal patency. Determining whether the fallopian tubes are

patent is part of the initial evaluation procedure in seeking the cause of infertility.

Technique involves detection of insufflated normal saline accumulating in the pouch of douglas, without differentiation of the sides.

The ability of ultrasound to detect patency of atleast one fallopian tube demonstrating free fluid in cul de sac was proved by more than one investigator. (Rasmussen 1986, Richman 1984, Sharma 1989).

The 'Sion Test' or Sonosalpingography used transvaginal sonography to confirm tubal patency by visualizing turbulance near the fimbrial end when a mixture of air and saline was injected through a foley catheter placed within the uterus. Each tube can be assessed separately without inherent risks of ionizing radiation as in hysterosalpinogography and risk of surgical and anaesthetic complications as in laparoscopy.

The sion procedure involves instillation of the pouch of douglas with approximately 300 ml of sterile normal saline to elucidate not only the pateny of the fallopian tube but to visualise the motility, the fimbriae and peritubal adhesions is present (Allahabadia).

Deichert et al recommended the additional use of pulsed wave Doppler in

hysterosalpingo contrast sonography.

By using medium such as suspension of micro particles of galactose in saturated galactose solution to which micro bubbles of air, a few microns in diameter, was adherent (SHU 454, Echovist Schering AG) The technique of transvaginal scanning using this substance was named 'Hystero salpingo contrast sonography' (Hycosy). The test was performed under general anaesthesia, and tubal patency was inferred if forward flow of echodense medium could be observed in the isthmic portion of the tubes, in the absence of fluid in a sacculated distal tube.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Richman et al suggested the term salpingography for a technique of testing tubal patency by instilling viscous dextran solution through the cervix. By observing pooling of fluid in pouch of Douglas on transabdominal scanning, they implied patency of atleast one tube. (Radiology 152 : 507-10, 1984).

Mitri et al compared saline instillation during outpatient transvaginal scanning with HSG and found ultrasound with saline hydrotubation more accurate in detecting hydrosalpinx than HSG. (British Journal of Obstet. & Gynae. 1991).

According to Shailesh Kore et al Transvaginal sonosalpingography is a simple, cost effective, non-invasive test, which can be used as a screening procedure for assessment of tubal patency in the initial working of infertile women. (Journal of Obst & Gyn India, April 2000).

Transvaginal ultrasound scanning has revolutionised infertility diagnosis and is fast becoming a routine adjunct to clinical examination in the clinic and office. Uterine and ovarian morphology can be displayed using the simplest scanners but the fallopian tubes and intrauterine lesions require image enhancement.

Various techniques of contrast enhancement have been proposed all of which involve instilling

a fluid medium into the uterine cavity via a cannula. Sonolucent media such as dextran or saline produce a negative contrast effect in the utero tubal lumen, while echo dense media incorporate micro bubbles of air impact an intense positive contrast.

Transvaginal sonographic tubal patency testing using air and saline as contrast media was used in a routine infertility clinic by Volpi E. et al. According to them the 'gold standard' for tubal patency was laparoscopy. In their study the results of tubal patency testing by transvaginal sonography were similar to these of Hysterosalpingogram but differed in 10% of cases from those of Laparoscopy. (Acta Obstet Gynaecol. 1994 Nov. 73(10); 797-801.

The most difficult problem is to rule out distal tubal occlusion without hydrosalpinx. Tubal patency testing with transvaginal sonography can be used safely as a first step examination of tubal patency (USG in O & G, 1996).

Dr. A.E. Oguntoyinbo et al state that sonosalpingography is a comparatively reliable, simple and relatively inexpensive diagnostic and therapeutic procedure in the management of female infertility. It is also relatively free of complications. With expected improvement in this techniques and future advances in sonographic tissue characterisation, it is believed that SSG will be the first line office based diagnostic procedure in the evaluation of tubal patency. (African Journal of Reproductive health, 2001)

As per Scanlan, Kathleen et al sonosalpingography can serve as a screening tool to determine whether the patient has atleast one patent tube, but it cannot determine which tube is patent. It can serve as alternative imaging study of radiographic hysterosalpingographic procedure. (Journal of women's imaging 2001)

Fleischer, Arthur et al states that sonosalpingography can be used for accurate assessment of tubal patency and to determine the presence or absence of significant tubal adhesions. Information regarding ovarian function and pathology offered by this technique adds value to the tubal examination. (Journal of women's imaging 2001).

According to study conducted by Gilliam Graves et al, the assessment of tubal patency, which is important in diagnosing tubal causes of infertility, was successful in 79% of woman when saline was used and in 92% of patients when a contrast agent was used. At present Hystero Salpingography is still a more reliable method for evaluating tubal patency, but it involves the radiographic use of contrast dye and at times, discomfort. Laparoscopy, another technique used to assess tubal patency, involves an anaesthetic and post operative discomfort. (CMAJ 2000 162 : 239-240)

According to a study conducted at Vanderbilt University Medical Center by Sono hysterosalpingography the diagnostic accuracy was 98% for submucosal fibroids, 96% for Polyps, 81% for synechia, Tubal patency successfully assessed in 79% with saline

solution and 92% with contrast agent.

Widemann R. et al stated that proximal tubal occlusion accounted for 2% tubal factor cases. It was of these types - nodular, non - nodular and pseudo occlusion. These can be diagnosed by laparoscopy or HSG. Falloposcopy was used either for confirmation or for treatment.(human Rep 11(5) P 986-91).

Taechakraichana et al compared diagnostic laparoscopy and transvaginal sonographic hydrotubation (TSH) in assessing tubal patency. In 80% of cases there was complete agreement between laparoscopy and TSH Partial agreement in 16.67% and no agreement in 3.33% of cases. TSH is a simple diagnostic procedure for screening tubal patency. However other confirmatory tests are needed if tubal occlusion is suspected (Journal of O & G Research, 1996).

As per Catalano GF et al there is no correlation between intra tubal damage and the extent and type of pelvic adhesions. Tubal mucosal factor is the most important prognostic factor for reproductive outcome. Assessment of tubal mucosa by salpingoscopy helps in selection of cases for tubal reconstructive surgery. 34-42% of patients with Hydro salpinx and 70-80% with periadenexal adhesions will get term pregnancy rate of 60% and 70% respectively. (1998 Tubal factor infertility P 673-82).

Glatstein et al describe the following practice among reproductive

endocrinologists. Younger physicians favour kruger morphology for semen analysis, rely on urine or blood LH for timing of PCT and use a less strict cut off for definition of a normal PCT. About half of all physicians use antibiotic prophylaxis before HSG and 90% rely on water-soluble dye for imaging. 80% of western US Physicians practice schedule diagnostic laparoscopy during follicular phase compared to 50% of East cost colleagues (Fert & Ster 70(2) : P 263-9, 1998).

Fifty nine percent of women who underwent hysterosalpingography and 47% after diagnostic laparoscopy, had procedure related physical complaints. Non - invasive techniques like post coital test, semen analysis, physical examination and basal body temperature recording were less stressful. Eimers J.M. et al are of the view that the role of HSG and diagnostic laparoscopy in the routine infertility work up needs to be reconsidered as they were found to be more stressful (Journal of Psych obst and Gyn 1997).

Inki P et al stated that sonosalpingography utilizing air and saline as a contrast medium is a reliable, simple and well-tolerated method to assess tubal patency in an outpatient setting. In addition, the procedure can be performed without prophylactic antibiotics using a regular pediatric Foley urinary catheter instead of an expensive hysterosalpingography catheter (Acta Obst & Gyn. 1998).

According to Tufefciec et al transvaginal sonosalpingography with its accuracy and safety, is a promising screening and diagnostic technique in the evaluation of

tubal patency on ambulatory basis.

According to study conducted by Rodriguez C et al sonosalpingography gives very similar results to hysterosalpingography and it is a low cost, reliable and comfortable examination method. It can be used for the primary investigation of infertility.

A.C. Fleischer et al states that combined use of sonohysterography and SSG in infertility patients with uterine or tubal factor disorder detects the pathology better. (Journal of USG in Medicine Vol 16).

According to a study conducted at Al-Azhar University Hospital Cairo TV - SSG is a simple procedure, it could be added to the usual conventional procedures to assess tubal patency as a new, easy and safe method and can be performed as an outpatient procedure in the routine infertility clinic.

Deichert et al described the case of positive contrast medium to visualise the fallopian tubes. (Human Reproduction 4:418-24, 1989).

According to Bacevac et al HSG is a useful test of tubal obstruction, the high false positivity might be due to tubal spasm and endometrical polyp in the area of the uterine opening of the tube, and also HSG and laparoscopy are the complementary

methods in the examination of tubal cause of sterility. (Diag. Value of HSG infertile women 2001 Jan – Feb).

MATERIALS AND METHODS

MATERIALS AND METHODS

This study was conducted at the Infertility clinic of the Department of Obstetric and Gynaecology, Government Rajaji Hospital, Madurai between the period of January 2004 – December 2004.

Among all the women attending the infertility clinic, 50 cases of either primary and secondary infertility were selected for the study after verifying the seminal parameters in the husband and seeking out male factor infertility.

Inclusion Criteria

To include a patient in this study the following criteria were to be fulfilled.

1. The age of the patient should be between 18-40 years.
2. Husband semen analysis should be normal.
3. The couple should have had unprotected intercourse for more than a year.
4. The patient should not suffer from any medical or hormonal dysfunction.
5. The menstrual cycle for all of them should be of normal duration and there should be no menstrual disturbances.

Exclusion Criteria

1. Those who have not completed one year of marriage life.

2. Sperm abnormality in the husband
3. Patient's suffering from obesity, goitre, hyper prolactinemia, hyperandrogenism and severe pelvic inflammatory disease were excluded from the study.

In all these patients, detailed history with respect to nature and duration of infertility and history suggestive of aetiological factors like PIH, TB, Previous operations etc were taken. Menstrual history, past obstetric history in case of secondary infertility and significant personal and past history were recorded. History regarding male factors of infertility was also taken.

The patient was subjected to a general, abdominal and bimanual pelvic examination to detect any obvious pathology. Vital parameters recorded, basic investigations done.

Routine investigations, husband's semen analysis and other relevant investigations were done in all these cases. In post menstrual prevolatory phase (Day 8) these patients were subjected to sonosalpingography and hystero salpingography was carried out on day 10 in department of radiology.

According to Oguntoyinbo et al the following sonographic features were regarded as evidence of tuba patency. Presence of free fluid in

i) Either of the adnexae, indicating patency of the ipsilateral fallopian tube.

ii) Both adnexae and around the pelvic parts of bowel loops.

iii) Fluid in the pouch of douglas alone and

iv) in all of the above sites.

Procedure of sonosalpingography

Transvaginal sonography was done on USG machine Sonata using 7.5 MHZ transducer. Informed consent was taken, bladder was emptied and after a pelvic examination the patient was brought to the edge of the table and a 8 F Foley's catheter was inserted transcervically just beyond the internal os. A new condom was slipped over the probe before each examination for reasons of hygiene. A small amount of coupling gel was applied to the inner surface of the top of the condom to ensure contact. Once the preparation was completed, the transducer was gently inserted into the vagina with the marker pointing anterior towards the pubic symphysis.

The 3 scanning manoeuvres used were

1. Side to the side movement within upper vagina for sagital imaging.
2. Transverse orientation for imaging in semiaxial / axial planes.
3. Cervical imaging by gradual withdrawal of probe. Images of the uterus with catheter inside were obtained. After scanning the uterus, left ovary and right

ovary, POD is visualized, absence of any fluid is confirmed.

About 30 – 40 cc of sterile saline was pushed through the Foley's catheter. Collection of fluid in the POD verified. Patients with bilateral tubal block complained of a sharp acute lower abdominal pain the moment the saline was injected. The catheter was then removed. The patients were allowed rest for a short period of time and then sent home on 5 day course of doxycycline and metronidazole.

Collection of fluid in POD indicated that the tubes were patent. Absence of fluid in POD was taken as tubal block. The limitation was that the side of block cannot be determined.

Procedure of Hysterosalpingography

Hysterosalpingography is a radiographic examination of the uterine cavity and fallopian tubes with injection of contrast medium under fluoroscopic control. The oily contrast media lipiodol and later lipiodol ultra fluid were used for many years, but have been largely replaced by water soluble contrast media which are generally considered safer. HSG is best performed at the end of the first week after the menstrual period. The isthmus is most easily distended at this time, and early pregnancy is avoided.

Several techniques and instruments exist, including insertion cannulae (e.g. Leech Wilkinson

cannula, Green Armytage cannula), suction cannulae (e.g. Malmstorm Westermann vacuum uterine cannula), and balloon catheters (e.g. Foley catheter, Sholkoff catheter). Catheter HSG is generally less traumatic and painful for the patient, and makes it also easier to rotate the patient after insertion of the instrument. The balloon of the catheter is usually inflated in the uterine cavity and pulled downward to the internal os to prevent leakage of the contrast medium. Demonstration of the cervical canal is achieved by injection of contrast medium during extraction of the catheter after deflation of the balloon. Nonfilling of a fallopian tube due to cornual spasm may be alleviated by intravenous injection of antispasmodic.

Contrast medium

- Water soluble contrast medium
- Sodium, Meglumine dial risoate volume 10

Equipment

1. Fluoroscopy unit with spot film device.
2. Vaginal speculum, vulsellum forceps and uterine cannula or 8F paediatric foley catheter.

Technique

1. The patient lies supine on the table with knees flexed, legs abducted.
2. Using aseptic technique the operator inserts a speculum and cleans the vagina and cervix with chlorhexidine.
3. The anterior lip of the cervix is steadied with the vulsellum forceps and the Leech Wilkinson cannula is inserted into the cervical canal.

4. Care must be taken to expel all air bubbles from the syringe and cannula, as these would otherwise cause confusion in interpretation. Contrast medium is injected slowly.

Films

1. First film has to be taken as the dye goes in and fills up the uterus.
2. 15-20 minutes after the first film second film has to be taken to see the periotoneal spill.

Informations obtained with HSG

1. Presence of peritoneal spill indicate tubal patency.
2. Absence of peritoneal spill indicates tubal block.

The advantage of HSG is that site and side of tubal block can be identified.

After care

It must be ensured that the patient has neither serious discomfort nor has significant bleeding before she leaves.

Complications

Due to the contrast medium

- ★ Allergic phenomenon – especially if contrast medium is forced into the circulation.

Due to the technique

1. Pain may occur at the following times
   a. Using the vulsellum forceps
   b. During insertion of the cannula
   c. With tubal distension proximal to a block
   d. With distension of the uterus if there is tubal spasm
   e. With peritoneal irritation during the following day, and upto 2 weeks.

2. Bleeding from trauma to the uterus or cervix.

3. Transient nausea, vomiting and headache.
   - ★ Intravasation of contrast medium into the venous system of the uterus results in a fine lace-like pattern within the uterine wall. When more extensive, intravasation outlines larger viens. It is of little significance when water soluble contrast media are used.

4. Infection – This may be delayed. Occurs in upto 2% of patients and more likely when there is a previous history of pelvic infection.

ANALYSIS OF THE STUDY

OBSERVATION

ANALYSIS OF THE STUDY OBSERVATION

The following observation were observed in ours study

1. Age distribution

Table 1

Age (year)	No. of cases	Percentage
20	1	2
21-25	20	40
26-30	18	36
31-35	10	20
>36	1	2
Total	50	100

2% (1/50) of women in the study group were 20 years of age. 40% were in the age group of 21-25 years, 36% in the age group belonging to 26-30 years. 20% were aged 31-35 years and only 2% were above 36 years.

Majority of the study group were in the age group of 21-30 years. This is the period during which the fertility rates are at its maximum.

2. Type of Infertility

Table 2

Type	Number	Percentage
Primary	47	94
Secondary	3	6
Total	50	100

Of the 50 case studies 94% (47/50) had primary infertility and only 6% (3/50) had secondary infertility. Of the three with secondary infertility one had three spontaneous abortions and one had previous ectopic pregnancy and underwent salpingectomy. The third patient had previous full term delivery.

3. **Duration of Infertility**

Table 3

Period	No. of cases	Percentage
2	3	6
3 years	10	20
4 years	10	20
5 years	3	6
> 6 years	24	48
Total	Total	100

6% (3/50) of the study group had married life of 1-2 years. Of this 20% (10/50) were married for 3 years, 20% (10/50) were married for 4 years, 6% were married for 5 years, 46% (24/50) of study group had married life of 6 and more than 6 years.

4. **Tubal factor infertility**

Table 4(a)

Tubal patency – diagnosis by

Sonosalpingography

Results	No. of patients	% of patients
Fluid in POD	45	90
No fluid in POD	5	10
Total	50	100

In 90% (45/50) Patients fluid was present in pouch of Douglas, which was indication of tubal patency. In 10% (5/50) of patients there was no fluid in pouch of douglas which was taken as tubal block.

Table 4(b)

Diagnosis by Hystero Salpingography

Results	No. of patients	Percentage
Presence of peritoneal spill	46	92
No peritoneal spill	4	8
Total	50	100

In 86% (43/50) of study group peritoneal spill was seen on both sides indicating that both tubes were patent.

In 8% (4/50) peritoneal spill was not seen on both sides indicating that both tubes were blocked. Out of this 1/4 had proximal tubal block and 3/4 had distal tubal block.

In 6% (3/50) cases unilateral tubal block was found, out of which 1/3 showed blockage on right side and 2/3 showed blockage on left side.

The advantage of Hysterosalpingogram is that site and side of tubal block can be identified.

5. Comparing the results of Sonosalpingography and Hysterosalpingography

Table 5

Procedure	Patent		Not patent	
	No.	%	No.	%
Sonosalpingography	45	90	5	10
Hysterosalpingography	46	92	4	8

Comparative study between the two procedures showed that results were almost similar. In 90% of cases, 'tubal patency was demonstrated by both the procedures : sonosalpingography and hysterosalpingography.

One case which showed false negative result by sonosalpingography which gave a positive result with hysterosalpingography.

Statistical Table

		Hysterosalpingography		Total
		Normal	Abnormal	

Sonosalpingo-graphy	**Normal**	TP 45	FP -	45
	Abnormal	FN 1	TN 4	5
		46	4	50

Sensitivity = $\frac{\text{True positive}}{\text{True positive + False negative}} \times 100$

= $\frac{45}{45+1} \times 100$

= 98%

Specificity = $\frac{\text{True negative}}{\text{False positive + True Negative}} \times 100$

= $\frac{4}{4+0} \times 100$

= 100%

Accuracy = $\frac{\text{True positive + True negative}}{n}$

= $\frac{45+4}{50} \times 100 = 98\%$

Positive predictive value = $\frac{\text{True positive}}{\text{True positive + false positive}} \times 100$

= $\frac{45}{} \times 100$

45+0

= 100%

Negative predictive value= True Negative x 100

True negative + false negative

= 4 x 100

4+1

= 80%

P = 0.5 (Not significant)

This comparative study shows that the

- ★ Sensitivity of the test is 98%
- ★ Specificity of the test is 100%
- ★ Positive predictive value is 100%
- ★ Negative predictive value is 80%
- ★ P=0.5 (not significant)

6. Associated pathology

Table 6

Pathology	Salpingography	Hysterosalpingo -graphy
Hydrosalpinx	3	3
Ovarian cyst	7	-
Uterine fibroid	2	2
Uterine anomaly	1	1

Certain associated features identified with sonosalpingography was also demonstrable with hysterosalpingography. In 6% of cases hydrosalpinx was identified with both Sonosalpingography and Hysterosalpingography.

Uterine fibroids were seen in 4% in both procedures. Bicornuate uterus was identified in 2% with both procedure.

Ovarian cyst which is an ultrasonogram diagnosis was diagnosed with Sonosalpingography alone because USG was used in this procedure.

DISCUSSION

DISCUSSION

Tubal pathology with tubal blockage is one of the most frequent cause of infertility in a women, hence tubal patency tests plays an important role in infertility work up.

In our study out of various procedures available for testing tubal patency, 2 tests namely sonosalpingography and hystero salpingography have been used and the results obtained with each procedure have been compared.

50 infertile women were included in our study who were registered at Department of Obstetric and gynaecology, Madurai Medical College, Madurai over a period of 1 year. (Jan 2004 to Dec 2004).

All patients underwent SSG on day 8 and HSG on day 10 in the department of radiology.

When the age group of the women with infertility were analysed it is found that 2% (1/50) of women in the study group were 20 years of age. 40% (20/50) were in the age group of 21-25 years. 36% were in the age group belonging to 26-30 years. 20% (10/50) were aged 31-35 years and only 2% were above 36 years.

Majority of study group (76%) were in the prime period of fertility i.e. 21-30 years, of the factors responsible for infertility tubal factor contributes 45% cause for infertility.

None of these patients gave any significant history regarding pelvic inflammatory disease. Asymptomatic and subclinical PID is the most common but preventable cause for infertility. This is due to higher incidence of C. Trachomatis among the socio economically poor younger age women (Basker Rao 1994). The damage to pelvic organs that occurs is irreversible and cannot be corrected by current techniques of treatment (Allan B Maclean 1995).

Of the 50 cases of studied 94% (47/50) had primary infertility and only 6% (3/50) had secondary infertility. This is in accordance with Insler who found the incidence of secondary infertility in 5-5.4% of the general population. (Insler V. et al 1993).

The duration of infertility varied between 2 years to 14 years in the study group.

The ability of ultrasound to detect patency of atleast one fallopian tube demonstrating free fluid in Cul de Sac was proved by more than one investigator. (Rasmussen 1986, Richman 1984, Sharma 1989).

In our study group by Sonosalpingography in 90% (45/50) of the patients fluid was present in the POD., which was indicator of tubal patency. In 10% (5/10) of patients there was no fluid in POD which was taken as tubal block.

Rodriguez found 72.7% of his patients had bilateral tubal patency, and in 27.3% the tubes were occluded, by SSG.

SSG revealed bilateral patent tubes in 60% of cases, and the remaining 40% cases showed either bilateral or unilateral block of the tubes (Rahman M, 2002).

When the same patients were subjected to HSG it was found that in 86% (43/50) of patients peritoneal spill was seen on both sides indicating that both tubes were patent.

In 8% (4/50) peritoneal spill was not seen on both sides indicating that both tubes were blocked.

6% (3/50) had unilateral tubal block out of which 1/3 showed blockage on the right side and 2/3 showed blockage on the left side.

The advantage of HSG is that the site of block could also be identified.

Of the 8% (4/50) who had bilateral tubal block 1/4 had proximal tubal block and 3/4 had distal tubal block.

Certain associated features identified with SSG was also demonstrable with HSG.

In our study in 6% of cases Hydrosalpinx was identified with both SSG and HSG.

Uterine fibroids were seen in 4% of both procedure. Bicornuate uterus was identified in 2% with both procedure.

Ovarian cyst which is an ultrasonographic diagnosis was diagnosed with SSG also because USG was used in this procedure.

According to A.C. Fleischer et al the diagnostic accuracy of sonohystero salpingography was 98% for submucous fibroids, 96% for polyps and 81% for synechiae.

Developmental uterine anomaly causing infertility may be congenital or due to DES exposure. Mullerian duct fusion anomalies could also occur (Rossatti et al 1998).

Fibroids are less common in this study group compared to Africans who present with multiple fibroids at a younger age (Whitefield C.R. 1995).

The efficacy of both the procedures in identifying tubal block were compared, and the study showed that the results was similar.

In 90% of cases, tubal patency was demonstrated by both the procedures (SSG & HSG).

One case which showed false negative result by SSG, which gave a positive result with HSG. This could be due to

1. Tubo cornual spasm
2. Endometrial bits blocking the tube
3. Inappropriate technique
4. Inexperience of human error

A comparison was made with the previous studies conducted in the evaluation of sonosalpingography and hysterosalpingography in the management of infertility.

Study	Year	Results in %			
		Sensitivity	Specificity	PPV	NPV
Dr. Pallavi Lalthe Birmingham Women Hospital, Edgbaston	March 1999	85%	85%	93%	72%
Oguntoyinbo, Department of Radio diagnosis, university of Ilorin, African journal of Rep. Health Vol 5 No. 1	August 2001	85.5%	96.8%	98.3%	75%
Shailesh Kore et al Dep. Of Obst & Gyn (TMMC & LTMG Hospital Mumbai)	1995-1996	100%	83%	97%	100%
Our Hospital study	2004 Jan – Dec	98%	100%	100%	80%

Hence Sonosalpingography can be used with its following advantages.

1. It is an office procedure, less time consuming and cost effective.
2. It is a non invasive procedure.

3. No anaesthesia is required.
4. It helps in diagnosing both uterine anomalies and pelvic pathology.
5. No radiation hazards are involved.

Hence Sonosalpingography can be used as a screening procedure for tubal patency. But the disadvantages has to be in mind.

1. Because of technical difficulties, side of tubal block cannot be determined.
2. Intra tubal pathology cannot be visualized.
3. Peritubal adhesions and mobility of the tube cannot be properly assessed.
4. There are false positive results in cases of massive hydrosalpinx.

Sonosalpingography is not a substitute for established tests like Hysterosalpingography or laparoscopy, but it can be done as a test in the initial work up of infertile women.

Laparoscopy and Hysterosalpingography can be deferred for about 6 months in patients in whom sonosalpingography showed patent tubes thus allowing us to concentrate other factors of infertility.

In patients with negative or suspicious findings on sonosalpingography, established methods like hysterosalpingography or laparoscopy can be done to confirm the diagnosis.

In patients with normal findings in these tests, further tests to detect defects in tubal functions like electron microscopic examination of microbiopsy specimen collected by salpingoscopy (Brosen & Vasquey, 1996) or Radionucleotide hysterosalpingography (Brundin et al, 1989) can be done.

SUMMARY

SUMMARY

In this study 50 infertile women who attended infertility clinic of Department of obstetrics and Gynaecology, Government Rajaji Hospital, Madurai were selected according to inclusion and exclusion criteria stated in methodology.

All patients underwent SSG on Day 8 and HSG on Day 10 in the Department of Radiology.

- 76% (38/50) of this study population were in the age group of 21-30 years.
- 90% (45/50) of them had delay in seeking help for infertility for more than 3 years.
- Of the 50 cases studied 94% (47/50) had primary infertility and only 6% (3/50) had secondary infertility.
- By SSG, in 90% (45/50) of patients tubal patency was detected. In 10% tubal block was detected.
- While doing HSG, in 86% (43/50) of patients bilateral tubal patency was detected. In 8% (4/50) both tubes were blocked.

- In 6% (3/50) of cases unilateral tubal block was identified.

- The advantage of HSG is that the site of block could also be identified.

- Of the 8% (4/50) who had bilateral tubal block 1/4 had proximal tubal block and 3/4 had distal tubal block.

- Comparative study between two procedures showed that the results were similar. In 90% (45/50) of cases tubal patency was demonstrated by both the procedures (SSG & HSG).

- One case which, showed false negative result by SSG, gave a positive result with HSG.

- SSG had a sensitivity of 98% and specificity of 100% in detecting tubal patency.

- The positive predictive value of the test was found to be 100% and negative predictive value was 80%.

- Certain associated features identified with SSG were : hydrosalpinx, ovarian cyst, uterine fibroid and uterine anomalies.

CONCLUSION

CONCLUSION

- In the assessment of tubal patency SSG proved to be 100% specific in identifying tubal patency.

- The accuracy, efficacy and positive predictive value of SSG and HSG are found to be almost similar.

- By Transvaginal sonosalpingography, in addition to tubal patency procedure, complete examination of the entire pelvis can be done, thus delineating uterus and ovarian abnormalities.

- Sonosalpingography performed with isotonic saline is an office procedure, less time consuming, non invasive and cost effective and no radiation hazards are involved.

- To conclude, for all infertility cases Sonosalpingography can be applied as screening test, and in patients with negative or suspicious findings on sonosalpingography established methods like hysterosalpingography or laparoscopy can be done.

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PROFORMA

PROFORMA

Couple Names : 1 Age : OP No. : IP No.:
2 Age :

Occupation : M IC No. :
F

Date of first Attendance :

Length of sub fertility : Primary :
Secondary :

Length of Time with Current Partner :

Female partner : History :

Menarche Cycle : Reg / Irregular

Bleeding (Scanty Heavy) Dysmenorrhoea P.V. Discharge
(Moderate) Yes / No

Inter menstrual bleeding Post Coital bleeding Dyspareunia

Contraception Yes / No Prev. PID Pre. STD

Past TB

Obst. History : No. of years since last delivery if any :

Live birth :

Spontaneous abortion :

Induced abortion :

Ectopic :

Molar pregnancy :

Gyn. History : Surgery :

General Health :

Previous investigations :

General Examination :

Date : LMP : Day of cycle :

B.P. : Wt. : Height :

Resp / CVS Thyroid Body Hair :

Breast : R/L

Pelvis : Vulva :
Vagina :

Cervix : Mucus :

Uterus : AV/RV Size : Normal/Enlarged/Mobile/Fixed

Tenderness : Smooth / Irregular

Male Partner

Maldecent : Infection / STD :

Mumps : Surgery :

Trauma : Varicocele :

Frequency of intercourse :

Any problem with intercourse

Alcohol : Smoker :

Previous pregnancy with other partner :

Semen Analysis : Volume :

Count :

Motility :

Morphology :

SONOSALPINGO GRAPHIC FINDINGS

Date of Menstrual Cycle :

Fluid in POD : Uterus : Size :

Present : Shape:

Absent : Anomaly : Septae:

Hydrosalpinx : Rt: Lt: Arcuate

Tubo Ovarian mass : Rt : Lt: Myoma

Endometrium Thickness

Polyp

Ovary Right Left

Ovarian Volume

Size

Follicles

Choc. Cyst

Functional Cyst

PCOD

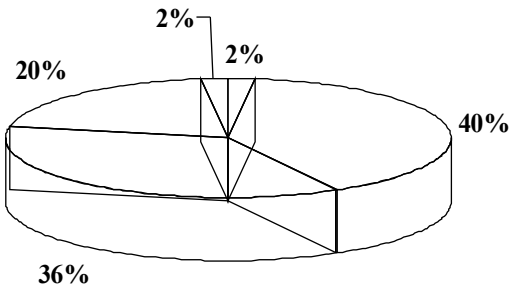
SSG Results Positive

Negative

HSG Results Positive

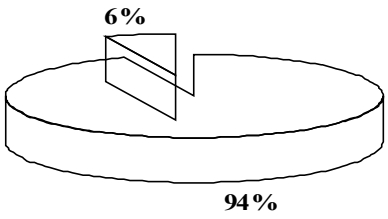
Negative If negative Site Side

Age distribution



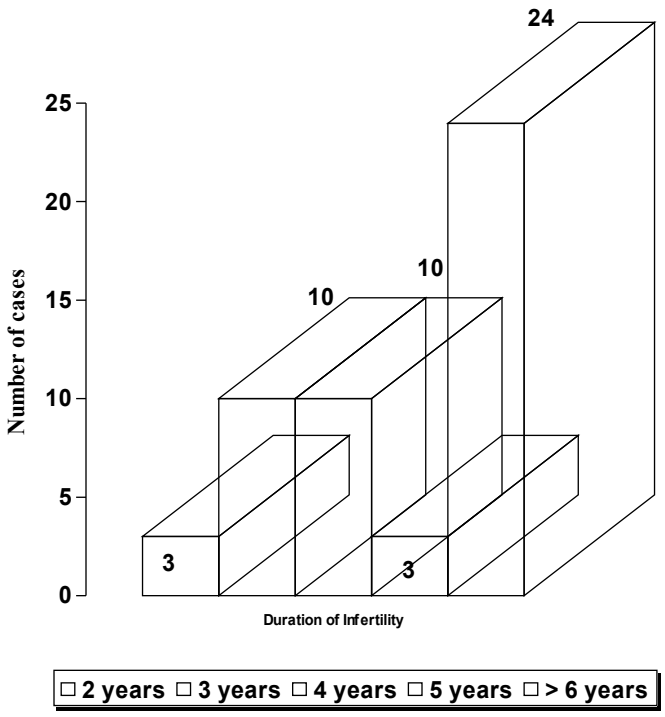
Age Group

Type of Infertility

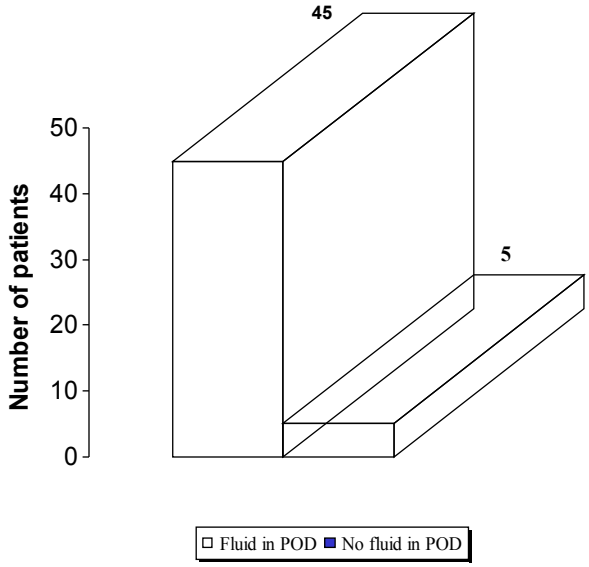


☐ Primary Infertility ☐ Secondary Infertility

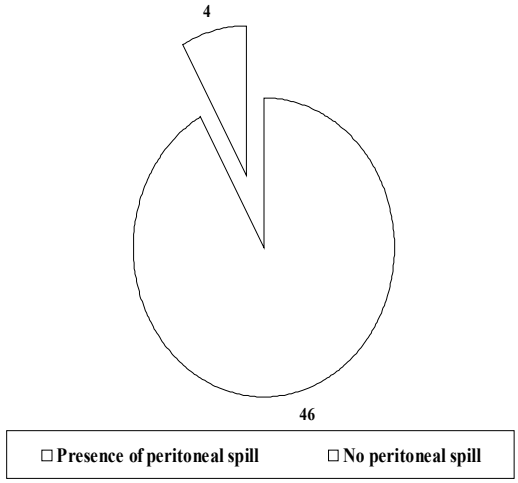
Duration of Infertility



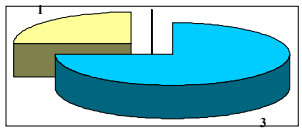
Tubal Patency – Diagnosis by SSG



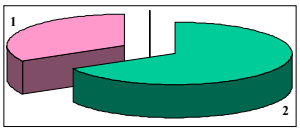
Diagnosis by HSG



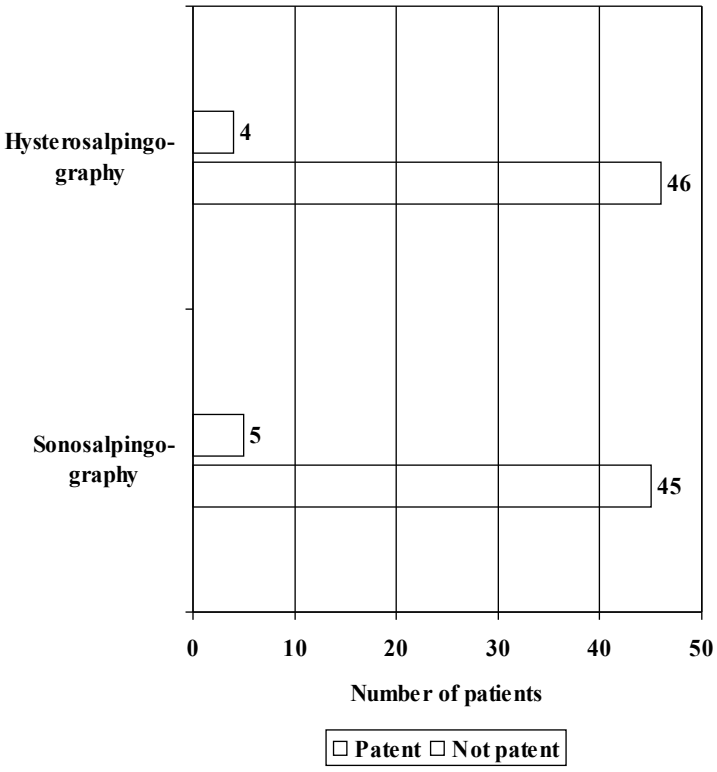
BILATERAL TUBAL BLOCK



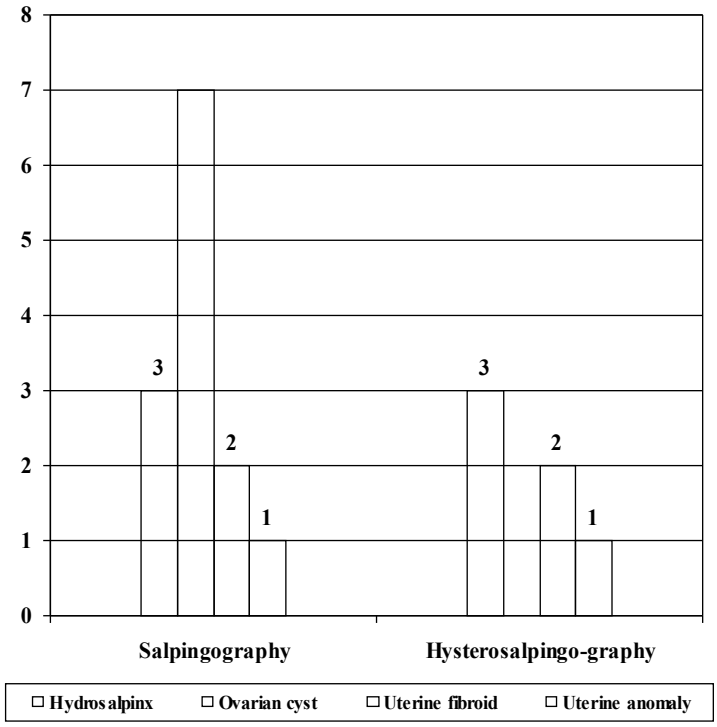
UNILATERAL TUBAL BLOCK



Results of
Sonosalpingography and Hysterosalpingography - Comparison

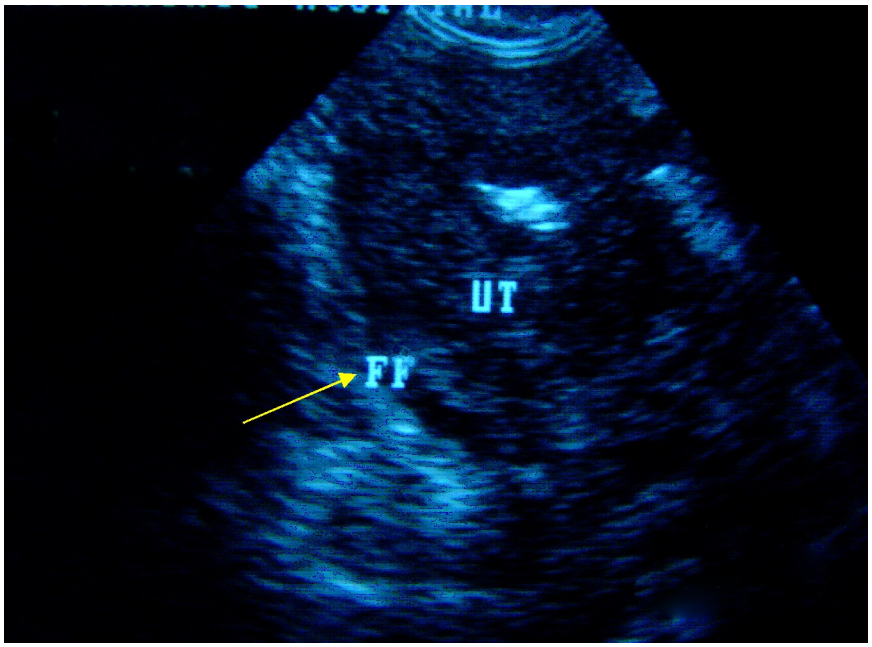


Associated pathology in sonosalpingography, and Hysterosalpingography.

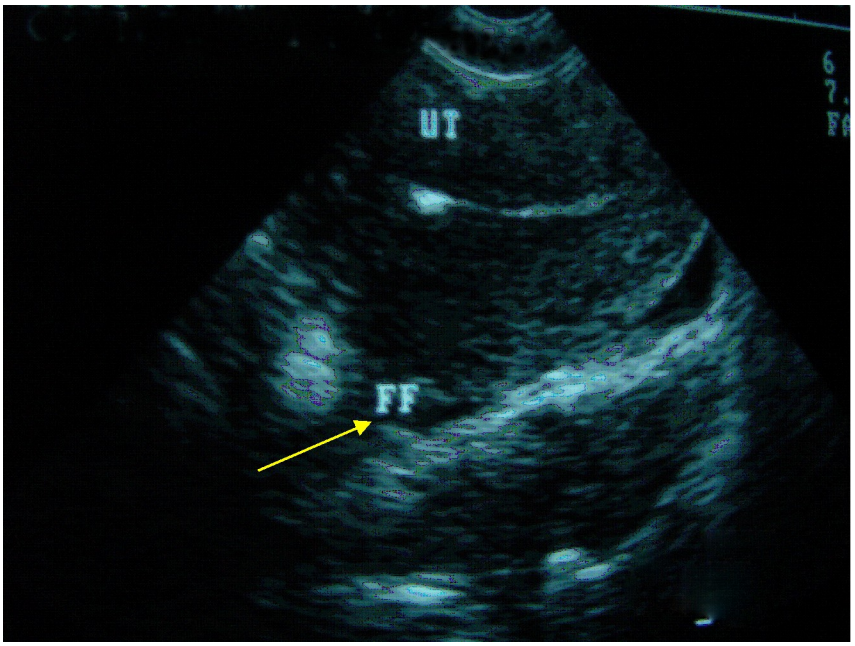


Fluid in the Pouch of Douglas

Cornoal View

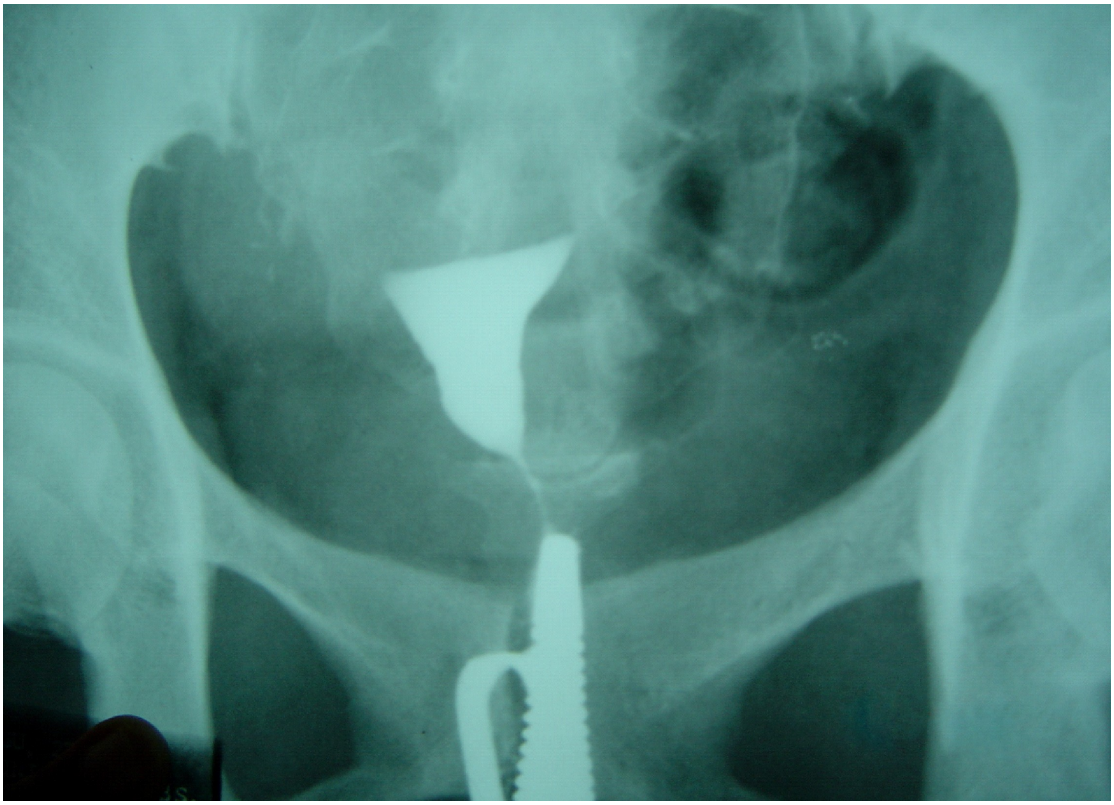


Sagital View

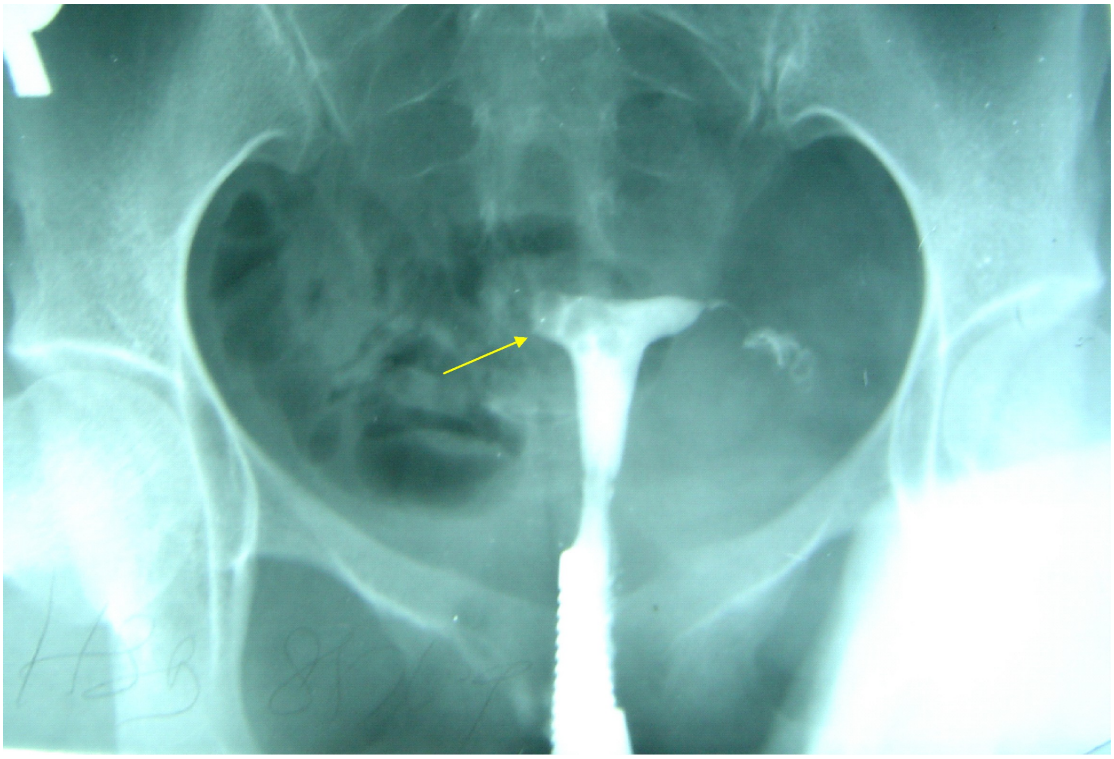


Bilateral Tubal Patency

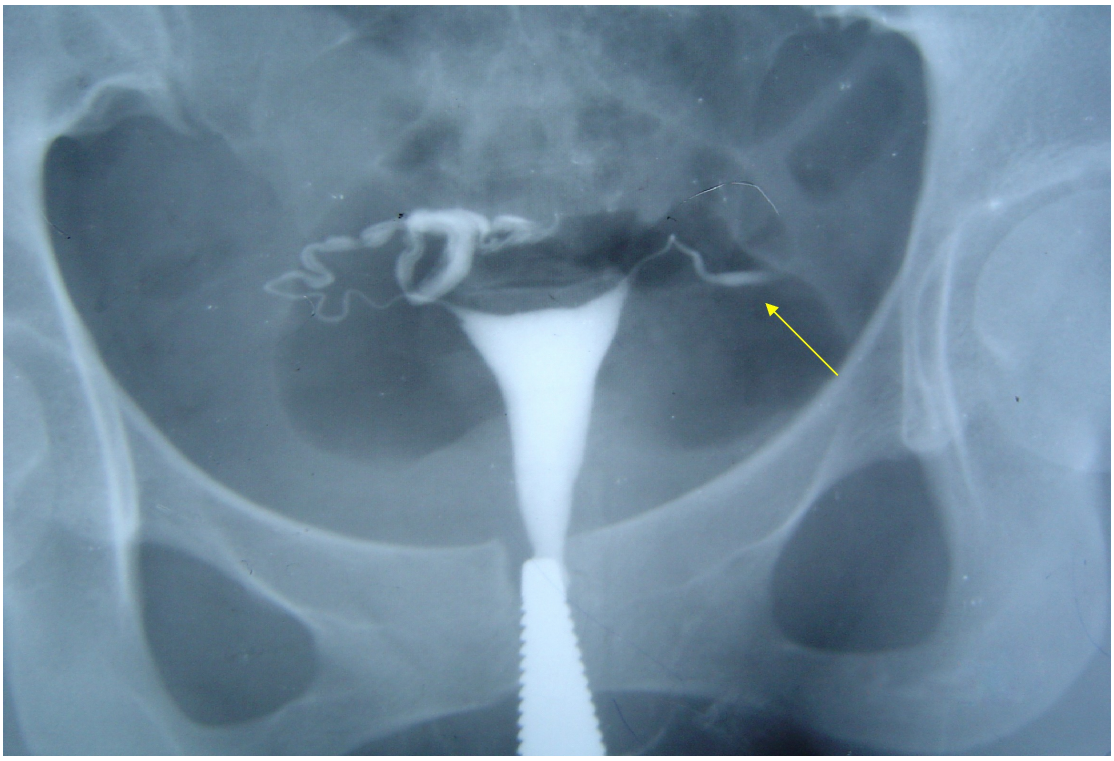
Biateral Cornual Block



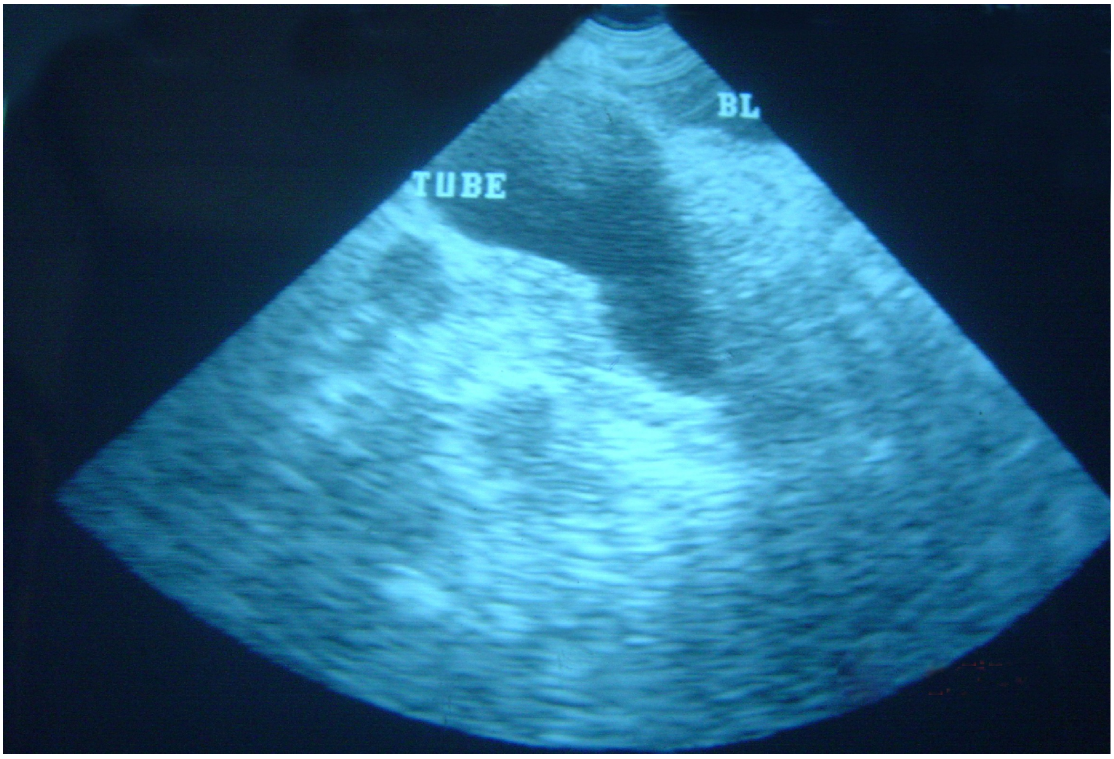
Right Cornual Block

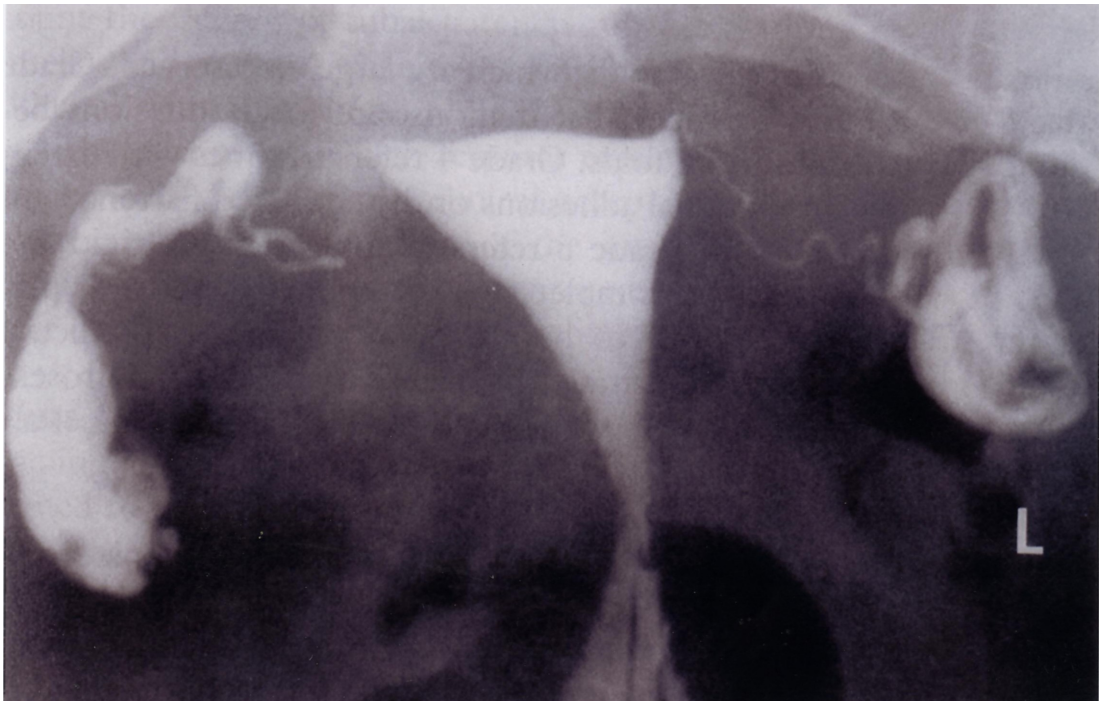


Left Ampullary Block

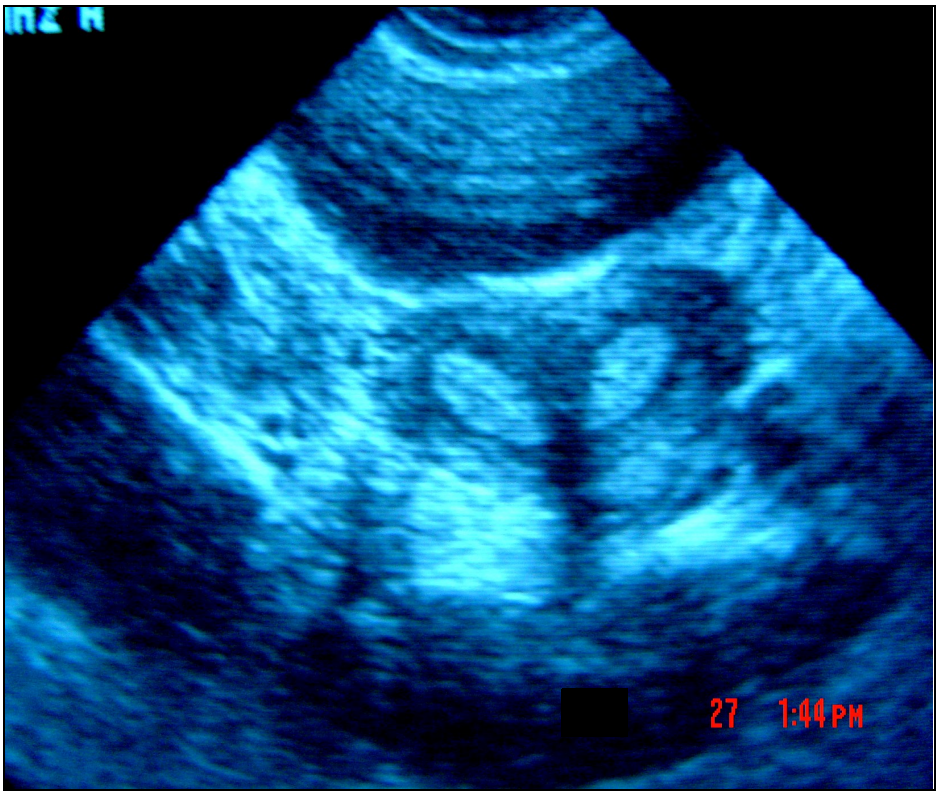


Hydro Salpinx



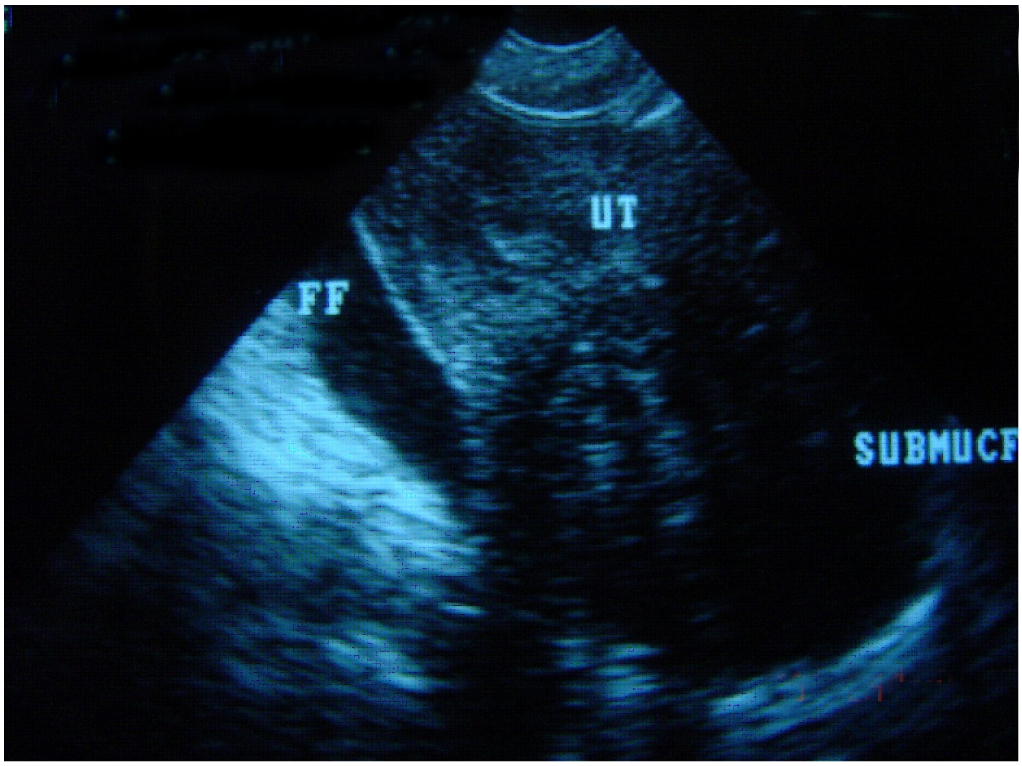


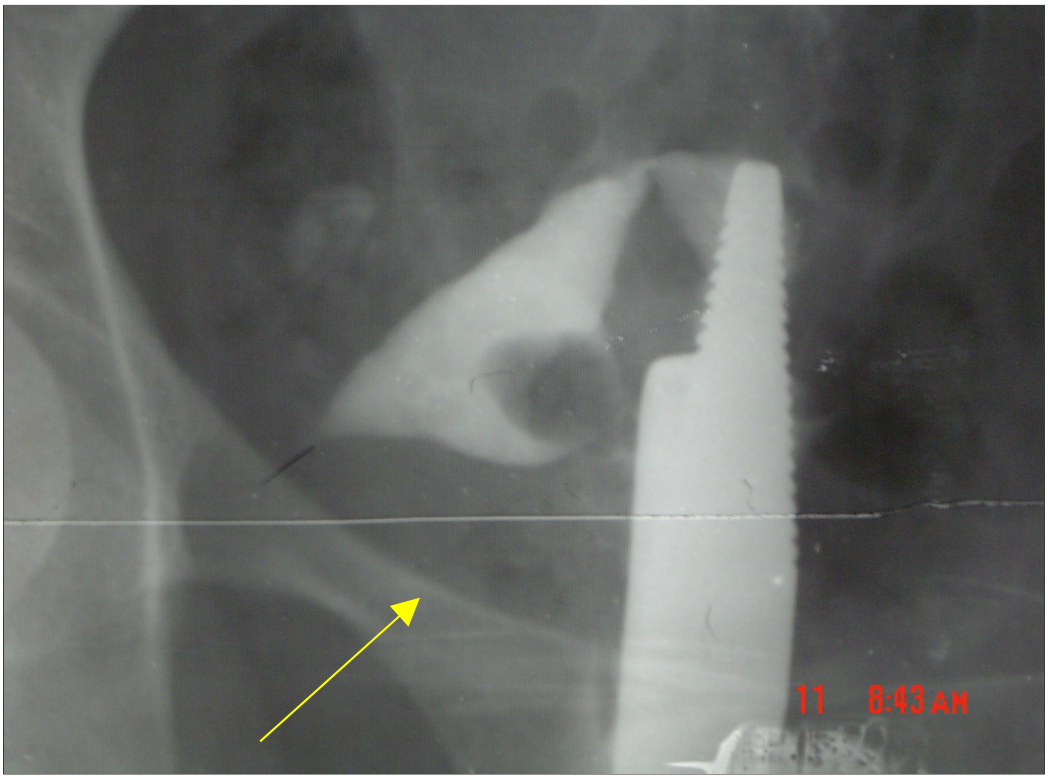
Bi Cornuate Uterus



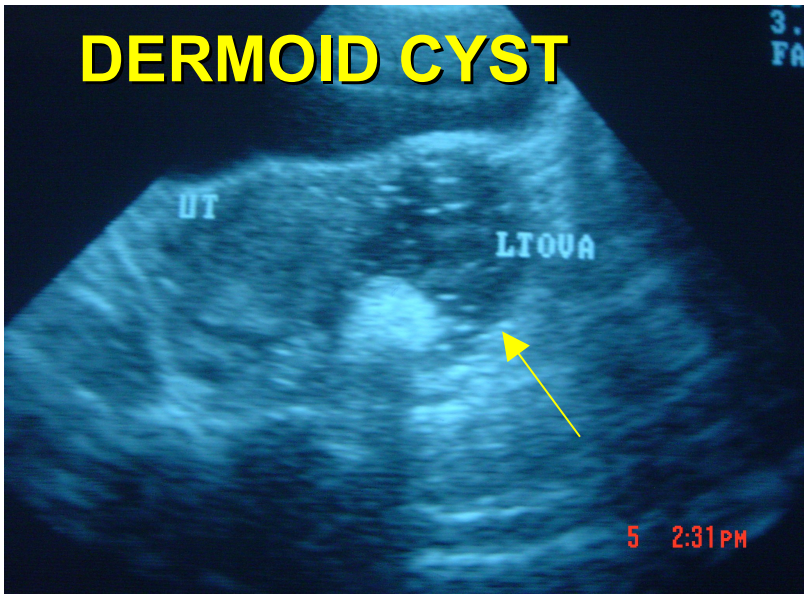

12 10:55 AM

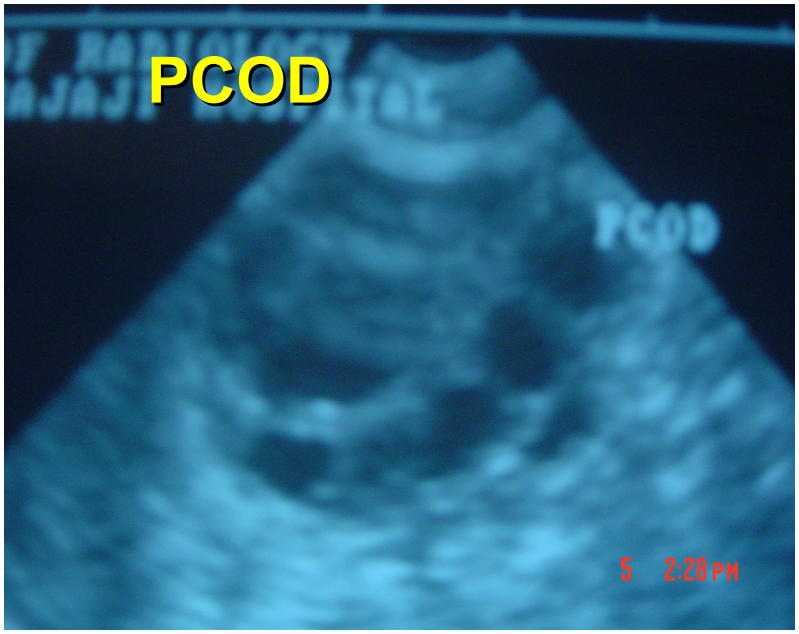
Submucus Fibroid






CHOCOLATE CYST
13cm
3.5MHz
FAR
5 2:30 PM


DERMOID CYST
UT
LTOVA
5 2:31 PM


PCOD
PCOD
5 2:28 PM